

# The Choice of Home Blood Pressure Monitoring Device Matters: Differences between Three Commercial Monitors Used in Finnish General Practice

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## Abstract

**Objectives:** The use of home blood pressure measurement in the follow-up of antihypertensive treatment is rapidly increasing. Published non-commercial comparisons or validation studies between different types of home monitors have been rare. We describe here the results from a study in which three home blood pressure monitors from two manufacturers were compared.

**Methods:** Three different upper arm automatic blood pressure measuring devices: Microlife BP 3AC 1-1, Microlife BP3AG1 and Omron M4-I were compared in a randomized study. It was carried out among 65 Finnish normo- and hypertensive people who used all three devices at home for one-week of blood pressure monitoring and measured their blood pressure twice both in the morning and in the evening.

**Results:** An about 2 mm Hg difference in systolic, diastolic and mean pressure was observed between Omron M4-I and the Microlife devices whereas the Microlife devices showed equal performance. A significant correlation in the mean pressure was observed between all three devices.

**Conclusions:** Although all these devices have passed the British Hypertension Society (BHS) qualification, the blood pressure monitoring results in this study showed that there may be a small blood pressure difference between the devices from separate manufacturers. Blood pressure monitoring results are most reliable when the same device is used consistently.

**Keywords:** Blood pressure control; Home blood pressure measurement; Blood pressure monitoring device

## Introduction

The use of home measurement in the follow-up of antihypertensive treatment is rapidly increasing. Compared with office blood pressure (BP) measurement home blood pressure monitoring provides better reproducibility, freedom from white coat effect and observer bias [1,2]. Home BP measurement results correlate better to end organ damage than the office measurement and home BP control overcomes many limitations of the traditional office BP measurement and there are no reasons why it should not be adopted increasingly [1-4].

According to the European Society of Hypertension (ESH), guidelines [3] validated electronic upper arm (brachial artery) devices have been shown to be most reliable in clinical practice and therefore their use is recommended for home blood pressure monitoring. There is a need for continuous monitoring of devices as only a minority of devices on the market has fulfilled independent validation criteria. The ESH has supported the establishment of a not-for-profit web site to provide updated lists of validated blood pressure measuring devices ([www.dableducational.org](http://www.dableducational.org)). Published non-commercial comparisons or validation studies between different types of home monitors have been rare [5-8]. We describe here the results from a study in which three home blood pressure monitors from two manufacturers were compared.

## Material and Methods

We examined three upper arm automatic blood pressure measurement devices; Microlife BP 3AC 1-1 and Microlife BP3AG1 by Microlife AG Swiss Corporation Espenstrasse 139, CH-9443 Widnau/Switzerland and Omron M4-I by Omron Healthcare Europe, Kruisweg 577, 2132 NA Hooffdorp, Nederland. These devices were

new and unused and given to the Turku University Hospital as a non-profit donation from the respective companies. All three studied blood pressure monitors were validated and have passed the British Hypertension Society criteria ([www.bhsoc.org](http://www.bhsoc.org)) [8-11]. They were used by Finnish hypertensive patients. Study patients were recruited consecutively from the outpatient clinic of the Department of Medicine of the Turku University Central Hospital. The study was approved by Hospital District of Southwest Finland and Turku University combined ethical board. Every patient undersigned a written consent to participate in the study.

The patients were instructed by an experienced nurse on how to measure their blood pressure by using those three devices. During one week the study patients measured their blood pressure using each of the three devices. BP was measured twice every morning and every evening in sitting position after a five-minute rest using as suggested by the European Society of Hypertension guidelines [3]. Patients used randomly the three devices according to given personal lists in daily envelopes. Altogether 84 measurements per patient and 28 measurements per device were performed. The patients wrote the results down in a special notebook.

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### Statistical analysis

The continuous variables are expressed as mean (SD). Database management and statistical analysis were performed using SPSS software, version 16.0. Group differences in continuous variables were assessed with paired Student's t test or one way analysis of variance as appropriate. The significance of correlation between the measurements performed by the three devices was determined by Pearson's correlation analysis.

### Results

Altogether 65 patients, 30 men and 35 women participated in the study. Mean age of the patients was 58.2 years (men 60.3, women 56.3 years). Twenty-five patients were treated by one antihypertensive drug, six by two, three by three and one patient with four different antihypertensive preparations. Thirty patients were untreated. Mean body mass index (BMI) of the study patients was 27.7 kg/m<sup>2</sup> (range 15.6-45.0), men 28.4 kg/m<sup>2</sup> and women 27.1 kg/m<sup>2</sup>.

Systolic, diastolic and mean blood pressure measured by using Microlife devices were significantly higher than those measured by Omron M4-I device (Tables 1 and 2). The mean pressures measured by the two Microlife devices did not differ from each other (Tables 1 and 2).

Table 3 shows the BP measurement accuracy between the studied devices in individual measurements. Regarding the observed difference between measured BP, all devices would have passed the European Society of Hypertension Protocol validation criteria ( $\leq 5$  mm Hg in 65%,  $\leq 10$  mm Hg in 90% and  $\leq 15$  mm Hg in 97% of all measurements) [12]. In 20% percent of the measurements, there was a difference of more than 5% between Omron M4-I and Microlife BP 3AC1-1 and in 29% between Omron M4-I and Microlife BP 3AG. A difference of more than 5% was seen in one third of the performed measurements between Microlife BP 3AG1 and Microlife BP 3AC1-1.

A significant correlation in mean arterial pressure was seen between the Omron M4-I device and the Microlife BP 3AC 1-1 ( $r=0.831$ ,  $p=0.001$ ) and Microlife BP3AG1 device ( $r=0.837$ ,  $p=0.0001$ ).

	Systolic pressure mmHg	Diastolic pressure mmHg	Mean pressure mmHg
Microlife BP 3AC1-1	131.1 (16.4) p=0.013	78.8 (8.8) p=0.0001	96.2 (10.1) p=0.0003
Omron M4-I	129.1 (17.1)	77.0 (9.1)	94.3 (10.5)
Microlife BP 3AG1	131.3 (17.5) p=0.0007	78.9 (9.1) p=0.0001	96.3 (10.6) p=0.0007

Microlife devices compared to Omron M4. No significant difference was found between the two Microlife devices.

**Table 1:** The mean systolic, diastolic and mean blood pressures (SD) during the one-week measurement period (n=65).

	Systolic pressure mmHg	Diastolic pressure mmHg	Mean pressure mmHg
Microlife BP 3AC1-1 vs Omron M4	+2.0 (7.2)	+1.9 (6.1)	+1.8 (7.4)
Microlife BP 3AG1 vs Omron M4	+2.1 (9.9)	+1.8 (6.0)	+2.1 (6.2)
Microlife BP 3AC1-1 vs Microlife BP 3AG1	-0.01 (13.2)	0.03 (5.0)	0.05 (5.0)

**Table 2:** The mean (SD) differences in the systolic, diastolic and mean blood pressures between the three devices during the one-week measurement period (n=65).

Observed difference	Omron M4-I vs Microlife BP 3AC1-1 1782 measurements	Omron M4-I vs Microlife BP 3AG1 1792 measurements	Microlife BP 3AG1 vs Microlife BP 3AC1-1 1782 measurements
mmHg	Percentage of measurements within the specified range		
[+5, -5]	80%	70%	66%
[+10, -10]	96%	93%	91%
[+15, -15]	99%	99%	97%
5	20%	29%	34%

**Table 3:** The BP measurement accuracy between the studied devices in individual measurements.

Also the mean arterial pressures of both Microlife devices correlated significantly ( $r=0.888$ ,  $p=0.0001$ ) (Figures 1-3).

### Discussion

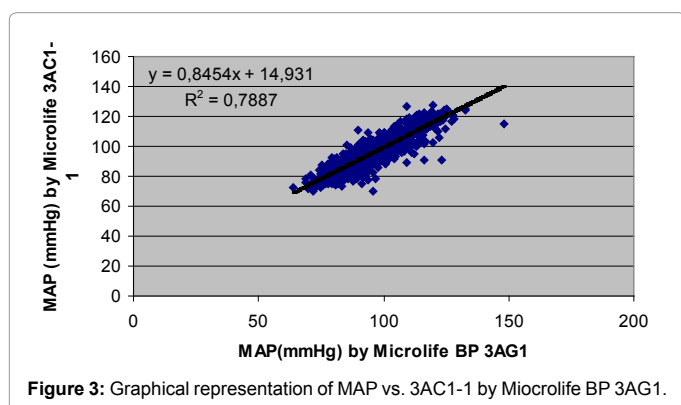
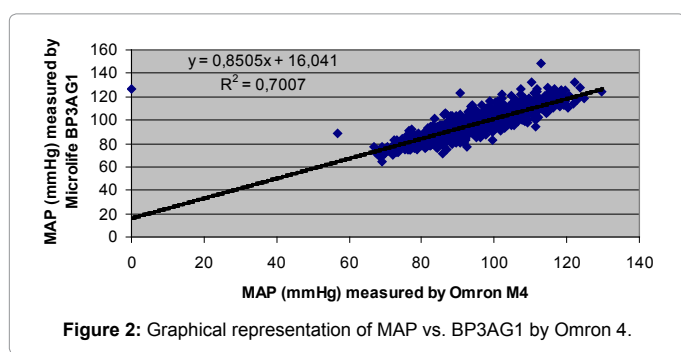
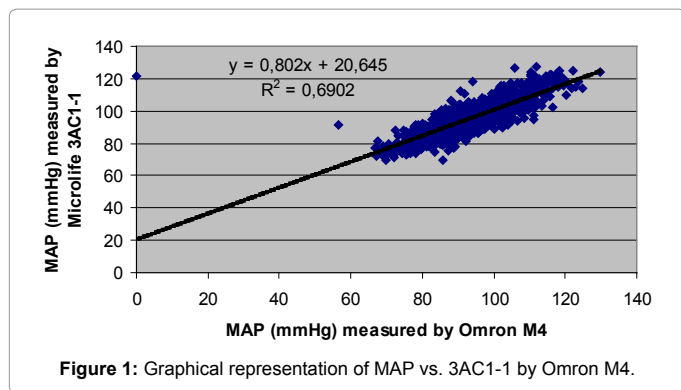
We observed a difference of about 2 mm Hg between the Omron and Microlife home blood pressure measurement devices. Both Microlife monitors showed quite equal mean blood pressure readings. On the basis of differences between individual measurements, the accuracy of all the studied devices was quite good and in that respect all of them would have been regarded as equal according to 2010 European Society of Hypertension Protocol validation criteria [12].

Although the patients were aware which device they used, the measurement sequence was prospectively randomized and the randomized order changed continuously throughout the study. Thus observed results reflect most probably real differences between the blood pressure measuring algorithms of the two manufacturers. Of course biasing is difficult to exclude completely in this kind of an open study but it is an improbable phenomenon. No reference sphygmomanometer was used and thus it is impossible to judge which monitor was closest to the actual value. Also the difference cannot be explained by the random inaccuracy by one device because altogether 20 individual devices per group were used.

The characteristics of our study patients match the average South-Western Finnish population [13]. Half of the patients were treated as hypertensive patients and half not-treated normotensive patients. Study population was not divided into two separate groups because the remaining groups would have been quite small for statistical analysis. The blood pressure during the first day in home monitoring has been shown to be the highest. Most probably, this is a result from diminishing white-coat effect. Improved patient-to-device compliance after the first days of monitoring may also have played a role and it highlights the importance of relaxed and familiar surroundings when blood pressure is measured. Thus the measurement as such probably did not affect on the results.

All devices in this study used oscillometric technique. The oscillometric method uses the small oscillations in cuff pressure to identify the systolic, mean, and diastolic pressures [14]. The mean BP is determined at the peak of the amplitude of the oscillations; the systolic BP, approximately 55% prior to the maximum; and the diastolic BP, approximately 85% after the maximum oscillations, although the exact points are proprietary to each manufacturer [15]. In this study, 2 mm Hg blood pressure difference was seen also in the mean pressure. However, we calculated the mean pressure from systolic and diastolic pressure because the devices did not show the mean pressure. Thus probably the calculation algorithms for systolic and diastolic pressures from mean pressure are equal to both manufacturers.

The Microlife devices measured about 2 mm Hg higher systolic,



diastolic and mean pressure than the Omron device. The 2 mm Hg difference in blood pressure is on population level quite significant but in individual level not so remarkable. Of course, it may lead to either starting or not starting antihypertensive medication depending on the choice of the device of the studied manufacturers. On the other hand, no differences were observed between measured BP using Omron or Microlife devices in a recent study with focus on the detection of atrial fibrillation in hypertensive patients [16]. Kewalbansing et al. [17] compared Omron HEM-SOLAR and Microlife BP3AS1-2 in Surinam and found that Microlife device underestimated systolic BP when compared with Omron and sphygmomanometer. The difference between individual measurements was greatest between the two studied devices from the same manufacturer. Although this difference fell within the validation range, this observation suggests that blood pressure measurement results from different devices even from the same manufacturer should be compared only with caution.

Comparing devices from different manufacturers is difficult and prone to give conflicting results. Although reference data is available,

the choice of the device is most often made by the patient and pure marketing aspects can influence the decision considerably. However, the most important thing is not the manufacturers name or the type of the validated device but that the patient uses regularly the device she bought and BP readings are compared only to ones obtained with the same device.

## Conclusion

Although the studied blood pressure monitoring devices were BHS approved and two came from the same manufacturer, they did not show equal values in this randomized comparison study. Although the differences were minor, they clearly matter and underline the clinical praxis that it is not recommended comparing blood pressure values if the measuring is not performed with the one and same device. As far as we know, this is one of the first studies to show this kind of difference between the home measurement devices of two different manufacturers.

## Conflicts of Interest

This is a pure academic study and the manufacturers of the studied devices were not involved in any part of it. None of the authors possess financial or other relationships that might lead to a conflict of interest.

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